



## Using IT to improve access, communication, and asthma in African American and Hispanic/Latino Adults: Rationale, design, and methods of a randomized controlled trial



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### ABSTRACT

Asthma morbidity is high among inner-city minority adults. Improving access to care and patient–provider communication are believed to be essential for improving outcomes. Access and communication in turn increasingly rely on information technology including features of the Electronic Health Record. Its patient portal offers web-based communication with providers and practices. How patients with limited resources and educational opportunities can benefit from this portal is unclear. In contrast, home visits by community health workers (CHWs) have improved access to care for asthmatic children and promoted caretaker–clinician communication.

We describe the planning, design, and methodology of an ongoing randomized controlled trial for 300 adults, predominantly African American and Hispanic/Latino, with uncontrolled asthma recruited from low income urban neighborhoods who are directed to the most convenient internet access and taught to use the portal, with and without home visits from a CHW. The study 1) compares the effects of the 1-year interventions on asthma outcomes (improved asthma control, quality of life; fewer ED visits and hospitalizations for asthma or any cause), 2) evaluates whether communication (portal use) and access (appointments made/kept) mediate the interventions' effects on asthma outcomes, and 3) investigates effect modification by literacy level, primary language, and convenience of internet access. In home visits, CHWs 1) train patients to competency in portal use, 2) enhance care coordination, 3) communicate the complex social circumstances of patients' lives to providers, and 4) compensate for differences in patients' health literacy skills. The practical challenges to design and implementation in the targeted population are presented.

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### 1. Introduction

Asthma, a chronic treatable disease, affects 18.7 million US adults [1]. Despite efficacious medications and national guidelines for management [2], asthma has a disproportionate impact on low income and minority adults, particularly African Americans and Puerto Ricans. In 2010, almost

4.5 million non-Hispanic Blacks reported having asthma [3]. Blacks have more than 3 times the emergency department (ED) visits, 2 times the hospitalizations, and 2 times the death rate for asthma compared to Whites [1]. Also in 2010, 3.6 million Hispanics/Latinos reported a diagnosis of asthma [4]. Puerto Ricans were 3.4 times as likely to die from asthma compared to all Hispanic/Latino groups [4]. Overall Hispanic/Latino adults were 30% more likely to be hospitalized for asthma than non-Hispanic Whites. Compared with children, adults are more likely to die from asthma, 65% of whom are women. There is much less research on asthmatic adults [1,5].

According to the Institute of Medicine, improvements in access and patient–provider communication are needed to reduce health

Abbreviations: CHW, community health worker; ED, emergency department; PT, patient portal training; PT + HV, patient portal training plus home visits.

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outcome inequities [6]. Comorbidities including hypertension, diabetes, and obesity, not infrequent in adults, increase the likelihood of adverse asthma-related outcomes and make access to care and patient–provider communication more complex. The patient portal of the Electronic Health Record, increasingly available to enhance patients' web-based communication with providers and practices, has the potential to improve communication and access.

The 2009 Health Information Technology for Economic and Clinical Health Act authorized the Centers for Medicare & Medicaid Services to provide reimbursement incentives for eligible professionals and hospitals who become “meaningful users” of certified EHR Electronic Health Record technology [7,8]. Among the core objectives of what is now called Meaningful Use is the promotion of patient portal (portal) use by patients and providers. The portal allows patients to access parts of their medical record, review test results, make appointments, request refills, and it provides a secure platform for electronic messaging with providers. However, the portal is not widely used by patients and is less available to low-income and minority patients [9]. Limited availability may actually exacerbate disparities in health care as medical practices increasingly use information technology for communication [10,11].

Community health workers (CHWs) making home visits in other settings have facilitated patient access and communication with health practices and overcome barriers to care coordination. They potentially can give clinicians insight into patients' lives and the social and economic barriers to access and communication, including barriers to using the portal. CHWs are widely accepted by patients as sharing cultural, economic and linguistic characteristics with them, for knowing the community, and for being able to build trust [12,13].

This study examines the benefits to low-income urban asthmatic adults, predominantly African American and Hispanic/Latino, of using the portal with and without home visits by CHWs who encourage and facilitate portal use, understand patients' social context, and enhance communication with the medical team. As advocated, we report its planning, ongoing delivery, and methodology, and the practical challenges to design and implementation in the targeted population, in order to enhance the value of this research [14].

## 2. Methods

### 2.1. Hypothesis and aims

The primary hypothesis is that asthma will improve in adult patients from the use of the portal and that the addition of home visits by CHWs will be particularly helpful for those with low literacy or language barriers. We compare portal training and home visits by a CHW with an active control of portal training (without home visits). The study is sponsored by the Patient-Centered Outcomes Research Institute as a response to its funding announcement “Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma.” The study is registered at ClinicalTrials.gov (NCT02086565). This protocol was approved by the University of Pennsylvania Institutional Review Board and all participants gave informed consent.

Specific aims test whether 1-year interventions randomizing adults with moderate to severe asthma to either patient portal training (PT) or patient portal training plus home visits from a CHW (PT + HV) result in 1) better within-group asthma outcomes (asthma control, quality of life, ED visits, hospitalizations) over time, 2) better asthma and general health outcomes (ED visits and hospitalizations) in PT + HV over PT, 3) more communication (use of the portal) and access (appointments made/kept) which mediate the interventions' effects on asthma outcomes, and 4) effect modification by literacy level, primary language, and ease of internet access of the interventions on outcomes.

### 2.2. Overview of the study design

Adults with uncontrolled asthma are recruited from outpatient primary care and specialty clinics that serve predominantly but not exclusively low income urban neighborhoods. PT consists of 2 visits: PP1 and PP2. At PP1 a CHW inquires whether internet access by computer, tablet, or smartphone is available at home, work, community hot spots, or participating clinics and together the participant and CHW confirm which is closest and most convenient (Fig. 1).

The CHW describes the portal and its functions and assists participants in requesting an activation code. At the second visit, called PP2, working with the same CHW, participants activate and access the portal and perform exercises in using it. PP1 and PP2 take place within 2 weeks of enrollment.

At enrollment participants are randomized 1:1 either to PT or PT + HV using randomly permuted blocks of varying block sizes and stratified by practice. Together with the use of opaque envelopes prepared by the project statisticians, this randomization plan facilitates allocation concealment to both health workers and eligible patients. We felt this concealment to be especially important because of the understandable preference among some patients for the added care and contact offered by home visits from CHWs. Participants all sign informed consent to enroll in the study and to undergo portal training and data collection. Those randomized to home visits sign a second consent form informing them that they are randomized to home visits and giving permission for these visits. Therefore, once randomization occurred, both worker and patient were unblinded to treatment. Only one member of a household can participate in the study. For those randomized to PT + HV there are 4 home visits: HV1, HV2, HV3, and HV4 (Fig. 1, Table 1). Those randomized to PT + HV work with the same CHW who conducted PP1 and PP2. At each home visit, the CHW ensures care coordination, including obtaining an asthma action plan that links patients' home and community with the clinic. The CHW provides standard asthma education, promotes communication with providers, encourages appointment keeping, and facilitates familiarity with health information technology. The final home visit, HV4, which occurs at 6 months reviews and encourages all of these activities. For the remainder of the year there are monthly follow-up phone calls or emails by the same CHW to encourage use of the portal and to check on the patient's asthma control (Table 1).

All participants are followed for at least 1 year with data collection at 3 month intervals and until the study's end. Data collection is carried out by a CHW who is not acting as a home visitor for this patient. The primary outcomes are patient-centered: asthma control, ED visits and hospitalizations for asthma or any cause, and asthma-related quality of life.

### 2.3. Design choices

#### 2.3.1. Randomized controlled trial

We chose a randomized controlled trial because randomization reduces the likelihood of bias from both known and unknown confounders [15]. Randomization is particularly important in a study involving health behavior where many complex influences are not well understood. The longitudinal design allows a real-life assessment as well as the efficiency of having baseline and pre-baseline measures as within-subject controls. Multicenter recruitment enhances generalizability as much as feasible beyond the practices and diversity of social circumstances.

The choices for the randomized trial, portal training and home visits, are attempts to adopt interventions to real-world settings. They are inspired by RE-AIM conceptualization framework [16] and the need for such implementation research [17]. Implementation of portal training and home visits is hypothesized to improve access and communication resulting in improved patient-centered outcomes including asthma control and asthma-related quality of life.

Portal training and home visits represent different approaches to improve patient–provider communication and care coordination as

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